REMARKS

Claims 1-18 are currently pending in the present patent application.

Claims 1-18 are amended.

Amendments to the Specification

Equation (39) is amended to correct a typographical error, and the occurrences of that equation appearing on pages 29 and 34 have been corrected to show division by parameter α. This renders equation (39) consistent with equation (37) which correctly shows division by parameter α. As such, no new matter has been added.

Claim rejections under 35 U.S.C. § 103

In the Office Action of December 9, 2011, claims 1-18 are rejected under 35 U.S.C. U.S.C. § 103(a) as being unpatentable over *Sinderby* (WO 02/056818) in view of *Euliano et al.* (US 7,425,201).

Amended claim 1 recites a method for determining a level of ventilatory assist to a ventilator-dependent patient for reducing the risk of respiratory muscle fatigue. A respiration-related feature of the ventilator-dependent patient is detected to produce a signal representative of the detected respiration-related feature (support for this feature can be found, for example, in the passage from page 29, line 29 to page 30, line 3 of the disclosure). A critical threshold of the respiration-related feature is calculated, wherein fatigue of a respiratory muscle of the ventilator-dependent patient develops when the signal representative of the detected respiration-related feature exceeds the critical threshold (support for this feature can be found, for example, in page 31, lines 1-19). The level of ventilatory assist to the ventilator-dependent patient is controlled to prevent the signal representative of the detected respiration-related feature to exceed the critical threshold and thereby prevent fatigue of the respiratory muscle to develop (support for this feature can be found, for example, in the passage from page 31, line 20 to page 32, line 4).

WO 02/056818 (hereinafter "*Sinderby*")

The Examiner indicates that *Sinderby* discloses a respiratory system (see Fig. 1) comprising a CPU 20 that acts as both a calculator and a controller for controlling a level of ventilation assist via ventilation tube 34 based on electrical signals from measurement probe 12 which measures or indicates a patient's inspiratory effort based on the comparison of the electrical signal to a desired threshold level.

The Examiner then acknowledges that *Sinderby* fails to explicitly relate the measured signal to the fatigue of a respiratory muscle. This has been argued in detail in Applicants' correspondence submitted in the USPTO on October 10, 2011.

US 7,425,201 (*Euliano et al.*)

In an attempt to overcome the deficiency of Sinderby to relate the measured signal to the fatigue of a respiratory muscle, the Examiner refers to Euliano et al. According to the Examiner, Euliano et al., discloses another respiratory system which relates a patient's inspiratory effort, as derived from a measured signal, to the fatigue of a respiratory muscle for the reason of the avoidance of respiratory muscle fatigue and to stimulate a more natural breathing process (see col. 4, lines 13-28).

The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Sinderby to incorporate the relation of the measured inspiratory effort to the fatigue of a respiratory muscle (if not already) in view of the teachings of the Euliano et al., to stimulate a more natural breathing process (see col. 4, lines 13-28).

Applicants respectfully traverse these rejections. In column 4, lines 13-28, Euliano et al., describes that measuring patient effort allows for appropriate ventilatory support that avoids respiratory muscle fatigue and respiratory muscle deconditioning, and that measuring imposed patient effort allows for more appropriate ventilatory support by allowing for the imposed effort

to be driven to zero to simulate more natural breathing and also as an important extubation criteria.

However, Euliano et al., describes no method of applying the measured values to control of a ventilator. In this respect, Euliano et al., simply indicates:

- in column 5, lines 45-49, that the processor unit operates to receive input parameters, process the input and provide an output corresponding to work of breathing, and that this output can be then used to control external devices, such as a ventilator; and
- in column 8, lines 5-12 that, during data collection for the training data, the ventilator is adjusted, for example, the pressure support level may be adjusted and measured work of breathing and the other parameters are continuously monitored while changing the ventilator.

To summarize, Euliano et al., measures values and indicates that such values can be used to control a ventilator to prevent respiratory muscle fatigue, without explaining how such control can be performed.

Accordingly, even if the combination proposed by the Examiner were made, Euliano et al., would teach Sinderby to calculate such values and adjust the ventilator to prevent respiratory muscle fatigue. To reach the present invention as newly, broadly claimed, further developments are required.

First of all a respiration related feature is measured.

Then, the values measured by Euliano et al., have to be translated into a threshold in the domain of the detected respiration-related feature above which respiratory muscle fatigue occurs. There is no description or suggestion to calculate or how to calculate such a threshold in Sinderby and Euliano et al., taken separately or in combination. Page 26, lines 20-23 of Sinderby describes that the level to be exceeded (threshold) is determined in terms of amplitude and duration is performed by manual adjustment supervised via visual feedback, or by automatically letting the level be relative to a mean noise level. It is believed to be unobvious to integrate and how to integrate the measured values of Euliano et al., into the calculation of the threshold of Sinderby.

Sinderby and Euliano et al., taken separately or in combination, further fail to teach control of the level of ventilatory assist to the ventilator-dependent patient to prevent the signal representative of the detected respiration-related feature from exceeding the critical threshold and thereby prevent fatigue of the respiratory muscle to develop.

Page 26, lines 20-26 of Sinderby describes that the level to be exceeded (threshold) is determined in terms of amplitude and duration and can either be performed by manual adjustment supervised via visual feedback or by automatically letting the level be relative to the above described mean noise level, and that an algorithm can further be used to trigger the respiratory sealing device 18 when the amplitude of an EMG signal segment of defined duration exceeds the threshold. Sinderby obviously describes a threshold to be exceeded.

The description of Sinderby, page 29, lines 7-9, discloses that, in response to EMG signals, airway inspiratory flow and/or pressure control commands are sent by the computer 20 for triggering a ventilatory support system (ventilator) through an interface (not shown). Page 27, lines 1-5 describes that (1) the duration of time that the EMG amplitude remains above the threshold level can be used to decide the duration of the breath e.g. the ventilatory support system can start and deliver a full breath independent of the presence of EMG activity that exceeds the threshold level, and (2) the algorithm can also be adjusted to discontinue the ventilatory support if the EMG amplitude drops below the threshold level, or in response to a decrease in amplitude that exceeds a given magnitude (decrement). This teaches away from controlling the level of ventilatory assist to the ventilator-dependent patient to prevent the signal representative of the detected respiration-related feature to exceed the critical threshold and thereby prevent fatigue of the respiratory muscle to develop.

At least for the above reasons, Applicant respectfully submits that the subject matter of claim 1 is patentable over the teaching of Sinderby and Euliano et al., taken separately or in combination. Withdrawal of the rejection is kindly requested.

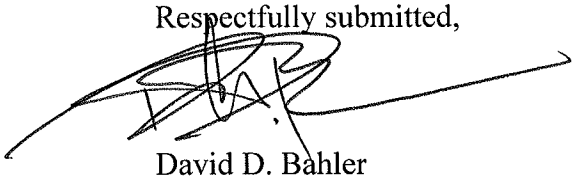
Claim 10 shares a comparable scope as that of claim 1; the above arguments have been presented in relation to claim 1 but equally apply to claim 10. Applicant thus submits that claim 10 is also patentable over the teaching of Sinderby and Euliano et al., taken separately or in combination.

Claims 2-9 depend directly or ultimately from patentable claim 1. Claims 11-18 depend directly or ultimately from patentable claim 10. Applicant respectfully submits that these claims should be found allowable at least because they depend on allowable bases.

In light of the foregoing amendments and remarks, favourable reconsideration and timely allowance is respectfully requested.

Should the Examiner believe that a phone interview could expedite prosecution of the present application, he is invited to contact the undersigned patent attorney.

Respectfully submitted,



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